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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,371	05/04/2005	Paul Howley	23208	9349

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THE FIRM OF KARL F ROSS
5676 RIVERDALE AVENUE
PO BOX 900
RIVERDALE (BRONX), NY 10471-0900

EXAMINER	
HURT, SHARON L	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,371	HOWLEY ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-42* is/are pending in the application.

4a) Of the above claim(s) *36-40 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28, 30-35 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04 May 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 20-35 and 41, in the reply filed on July 28, 2006 is acknowledged. The traversal is on the ground(s) that there is a common technical feature that distinguishes over the prior art and links all of the claims. This is not found persuasive because Group I is drawn to a recombinant poxvirus which is the special technical feature whereas Group II, III and IV are drawn to methods of making components therefore they do not share the same technical feature. Group V is drawn to a cell which does not share the same technical feature. The requirement is still deemed proper and is therefore made FINAL.

Claims 36-40 and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 28, 2006. Claims 20-35 and 41 are pending and under examination.

Claim Rejections - 35 USC § 112/101

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "are the same" fails to distinctly claim the subject matter of the claim invention. It is not clear what "same " is compared to or referring to in the claim.

Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim contains the trademark/trade name *MVA-BN™*. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an adjuvant and, accordingly, the identification/description is indefinite.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "as vaccine or medicament". It is not clear what structure the phrase is meant to impart.

Claim 38 provides for the use of the recombinant poxvirus, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 38 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex*

parte Dunki, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

It is not clear from the disclosure that deposits of Claim 29 meet all the criteria set forth in MPEP 608/01 (p)(C), items 1-3. Assurance of compliance may be in the form of a declaration or averment under oath. A suggested format for such a declaration or averment is outlined below:

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant=s agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that ensure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.

6. States that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.

7. Acknowledges the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.

8. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, name and address of the depository, and the complete taxonomic description. As a possible means of completing the record, applicants may submit a copy of the deposit receipt.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant

may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years. Or 5 years after the last request for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claims 20-23 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite "derivative" which is not clearly described in the specification. For example claim 20 recites "derivative or subsequence and wherein the derivative of the cowpox promoter is a sequence that has a homology of at least 60% when compared to the sequence of SEQ ID NO: 1 and/or a sequence in which not more than 6 nucleotides are substituted, deleted and/or inserted into SEQ ID NO: 1, wherein the subsequence of the ATI promoter has a length of at least 10 nucleotides of the sequence of SEQ ID NO: 1".

This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that Aapplicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117). A review of the language of the claim indicates that these claims are drawn to a genus, i.e. "a promoter or derivative thereof".

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species

encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.

There is a single species of the claimed genus disclosed that is within the scope of the claimed genus, *i.e.* "ATI promoter". The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species that are not further described. There is substantial variability among the species. In the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus, which is "a derivative thereof". One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus. The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20-28, 31-35 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by Pickup et al. (US Patent No. 5,443,964).

The claimed invention is drawn to a recombinant poxvirus comprising in the viral genome at least two expression cassettes, each comprising the cowpox ATI promoter or a derivative thereof or a subsequence of the ATI promoter or the derivative thereof and a coding sequence, wherein the expression of the coding sequence is regulated by said promoter, derivative or subsequence and wherein the derivative at the cowpox ATI promoter is a sequence that has a homology of at least 60% when compared to the sequence of SEQ ID NO: 1, wherein the subsequence of the ATI promoter has a length of at least 10 nucleotides of the sequence of SEQ ID NO: 1 and wherein the promoter, derivative or subsequence has the biological activity of being active as a promoter, wherein the activity of being active as a Vaccinia virus late promoter, wherein the promoter, derivative or subsequence comprises nucleotides 25 to 29 or 22 to 29 of SEQ ID NO: 1, wherein the promoter, derivative or subsequence in the recombinant poxvirus are the same, wherein at least two expression cassettes are inserted into the same insertions site in the poxvirus genome, wherein the promoter in at least one of the expression cassettes has the sequence of SEQ ID NO: 1, wherein the promoter in at least one of the expression cassettes is a derivative of the ATI promoter or a subsequence of the ATI promoter or a derivative thereof, wherein the poxvirus is an orthopoxvirus or avipoxvirus, wherein the orthopoxvirus is a vaccinia virus consisting of canarypoxvirus and fowlpoxvirus, wherein at least one of the coding sequences codes for at least one antigen, antigenic epitope, and/or a therapeutic compound,

wherein the recombinant poxvirus is a vaccine or medicament, wherein a vaccine or pharmaceutical composition comprises the said recombinant poxvirus, wherein said recombinant poxvirus is used for the preparation of a vaccine or medicament, and a method for the production of said recombinant virus comprising the step of inserting at least two expression cassettes into the genome of a poxvirus.

Pickup et al. (hereinafter Pickup) teaches about a vector and methods for making and using the vector. Pickup also teaches about elements derived from high level of expression of a gene of the cowpox virus wherein the elements used to obtain high levels of expression of the genetic material are inserted into the poxvirus expression vectors (Col. 1, lines, 5-13). Pickup teaches the sequence containing the initiation codon of the gene is the sequence shown in FIG. 1, which has 100% homology with SEQ ID NO: 1 of the instant invention (Col. 6, lines 42-43). Pickup teaches that usually the most strongly expressed genes of a virus are the late genes, which encode the major protein components of the virus particles (Col. 5, lines 16-18). Pickup also teaches about A-type inclusions or "ATI" which may or may not contain virus particles (Col. 5, lines 36-38 and 40-41). Pickup teaches about the late genes of vaccinia virus that have short sequences (15-30 bp) (Col. 2, lines 29-34). Pickup also teaches about other poxviruses such as avipoxvirus including fowlpoxvirus and canarypoxvirus (Col. 1, lines 41-42). Pickup teaches that these vectors have been designed to allow for simple insertion of cloned genes such as poxvirus-derived elements (Col. 8, lines 46-48). Pickup also teaches that the use of poxviruses containing vectors as a vaccine (Col. 8, lines 60-62).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20-28, 30-35 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickup et al. (US Patent No. 5,443,964) as applied to claims 20-28, 31-35 and 41 above, and further in view of Blanchard et al. (Journal of General Virology, 1998, Vol. 79, pages 1159-1167). The claimed invention as described above wherein the vaccinia virus is a modified vaccinia virus strain Ankara (MVA), , wherein at least one expression cassette is inserted in a naturally occurring deletion site of the MVA genome with respect to the genome of the vaccinia virus strain Copenhagen.

The teachings of Pickup are described above. Pickup does not teach the use of MVA or the strain Copenhagen.

Blanchard et al. (hereinafter Blanchard) teaches about modified vaccinia virus Ankara (MVA), MVA 575 and MVA strain Copenhagen. Blanchard teaches that recombinant MVA is a promising human vaccine candidate (Abstract). Blanchard also teaches about vaccinia virus strains Copenhagen and MVA 575 (page 1161, 1st column, 1st full paragraph and 2nd column, 1st paragraph).

Pickup teaches about recombinant poxvirus and ATI promoters. Blanchard teaches about the use of MVA. It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use MVA or vaccinia virus strain Copenhagen. The person of ordinary skill in the art would have been motivated to make that (those)

modification(s) because Blanchard teaches that MVA is a promising human vaccine candidate, and reasonably would have expected success because of the teachings of Pickup and Blanchard.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

December 8, 2006

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600